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09/470,276	12/22/1999	RICHARD KOLODNER	157/47483-C	5964

7590 01/09/2002

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 01/09/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/470,276

Applicant(s)

Kolodner et al

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Dec 19, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6-8, 10, 12, and 39-45 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 4, 39, 40, and 42 is/are allowed.
- 6) ☒ Claim(s) 3, 6-8, 10, 12, 41, and 43-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on December 19, 2001, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/470,276 is acceptable and a CPA has been established. An action on the CPA follows.

### ***General***

2. Claims 2-12 utilize the transitional term "having". Because this term lacks any particular meaning in the patent literature, the examiner will interpret "having" as being equivalent in scope to the open term "comprising".

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3, 6-8, 10, 12, 41 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

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Here, the new limitation of "cannot be selected only from base pairs 1908-2900" in claim 3 appears to represent new matter. A careful review by the examiner of the cited pages 51-52 of the specification failed to identify direct support for this new negative limitation. As noted by MPEP 2173.05(I),

" Any negative limitation or exclusionary proviso must have basis in the original disclosure. See Ex parte Grasselli , 231 USPQ 393 (Bd. App. 1983) aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement."

The MPEP indicates that express basis for exclusion is required and the currently identified section of the specification does not provide such express basis. Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter. Page 51 does provide basis for a claim to fragments selected from nucleotides 1-1908, however.

5. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by "exon is 221 basepairs" in claim 45 because the particular exon is not identified.

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It is vague and indefinite what is meant in claim 45 by "combinations thereof" with regard to intron sequences, since more than one intron is permitted by the "at least one" language already. It is unclear if this permits introns in non-canonical locations.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 3, 6, 8, 41 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Cross et al (Genbank Accession No. Z57284 (18 October 1995)).

Cross teaches a sequence which is 179 nucleotides in length and which has more than 17 nucleotides identical to SEQ ID NO: 1 and therefore is a fragment comprising a 17-mer of SEQ ID NO: 1. As the alignment below shows:

H.sapiens CpG island DNA genomic MseI fragment, clone 170b6, forward read cpg170b6.ft1a  
Length = 179  
Score = 168 bits (85), Expect = 6e-39  
Identities = 105/113 (92%)  
Strand = Plus / Minus

```
Query: 109 aggaggaagataagcgcgtagggctggggctcctggcgcggtggttgccagaggcagagaca 168
      |||
Sbjct: 179 aggaggaagataagcgcgtaggnctggggctcctggcgcggtggttgccagaggcagagaca 120
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***Allowable Subject Matter***

8. Claims 2, 4, 39, 40 and 42 are allowed.
9. The following is a statement of reasons for the indication of allowable subject matter: The claimed sequences are novel and unobvious over the cited prior art.

***Response to Arguments***

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the morning are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**Jeffrey Fredman**  
**Primary Patent Examiner**  
**Art Unit 1655**

January 9, 2002